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Transformational Medical Technologies Initiative (TMTI)

"To protect the Warfighter and the Nation from biothreats"



Advanced Planning Briefing to Industry

May 7-8, 2009



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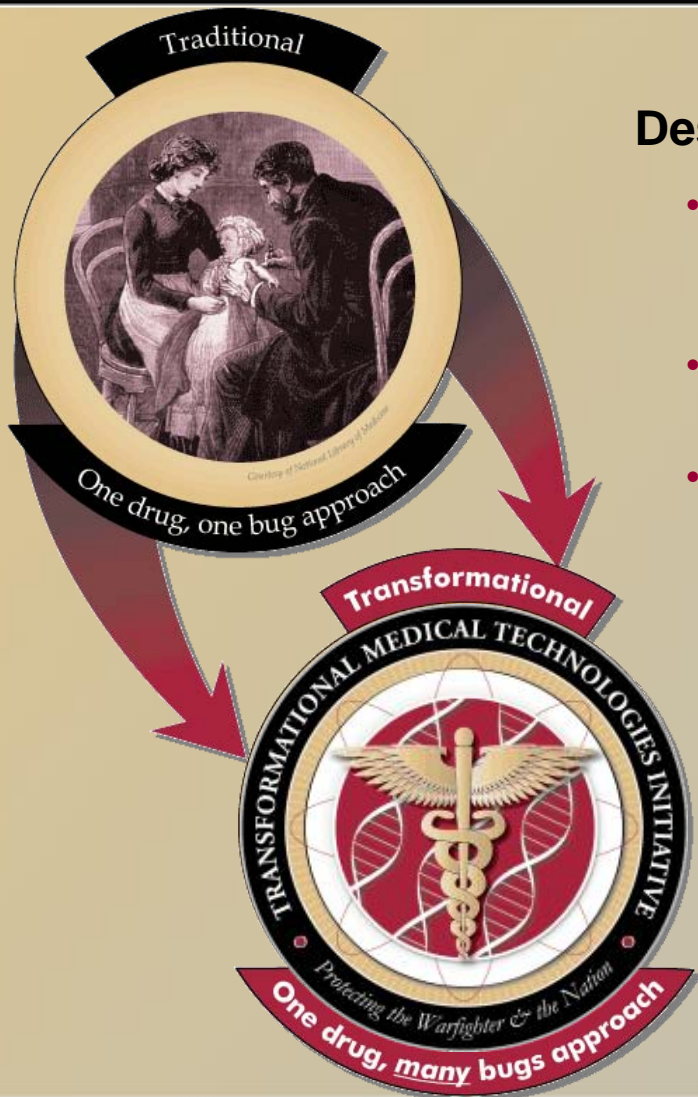
Mission



Protect the Warfighter from bioengineered or newly emergent biological threats by providing a response capability from identification of pathogens through the development of Medical Countermeasures (MCM).

- TMTI is especially focused on advanced biological threat agents
 - *de novo* or genetically engineered pathogens
- Requirements derive from:
 - Quadrennial Defense Review (QDR) – 2006
 - Chemical and Biological Defense's Medical Research, Development, Test & Evaluation Plan – December 2007

TMTI Delivers Innovative Solutions to the Warfighter



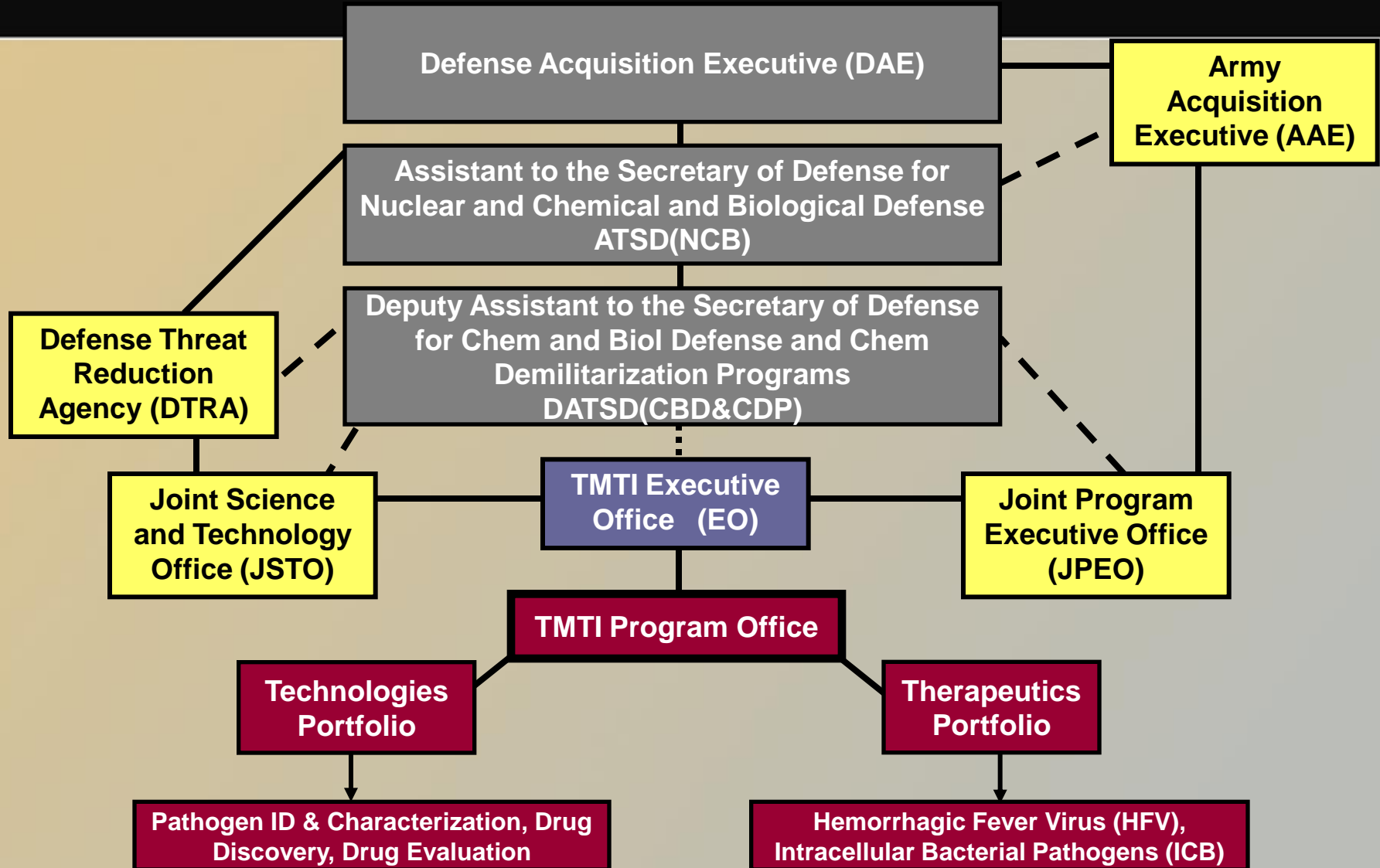
Designed to spur innovative research to develop:

- **Technologies** to identify unknown pathogens and rapidly develop medical countermeasures to newly identified threats
- Pathogen identification, characterization, and evaluation system
- **Broad-spectrum countermeasures** (one drug, many bugs)

TMTI is an initiative that will translate into a program to produce medical countermeasures that are:

- FDA approved
- Broad spectrum
- Produced using an approach rapidly adaptable to new threats

Organization Chart

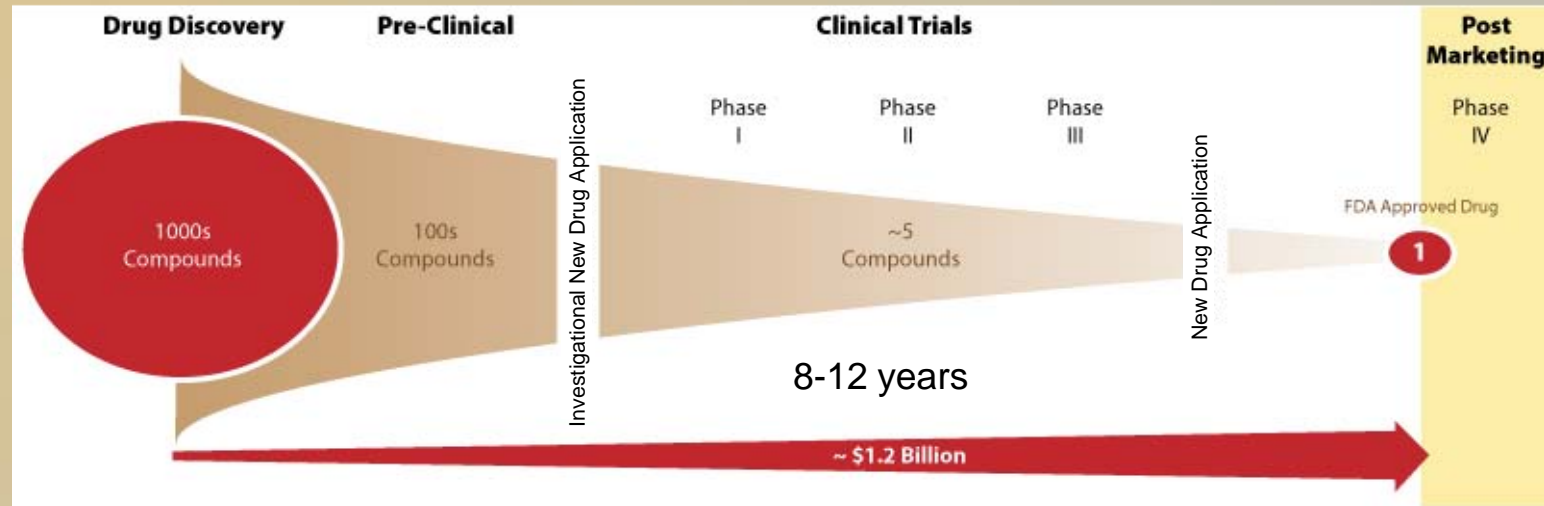


Commercial Drug Development Strategy

Limited Flexibility, Limited Responsiveness, Nonlinear



- The traditional “one drug, one bug” strategy is designed against known pathogens and diseases



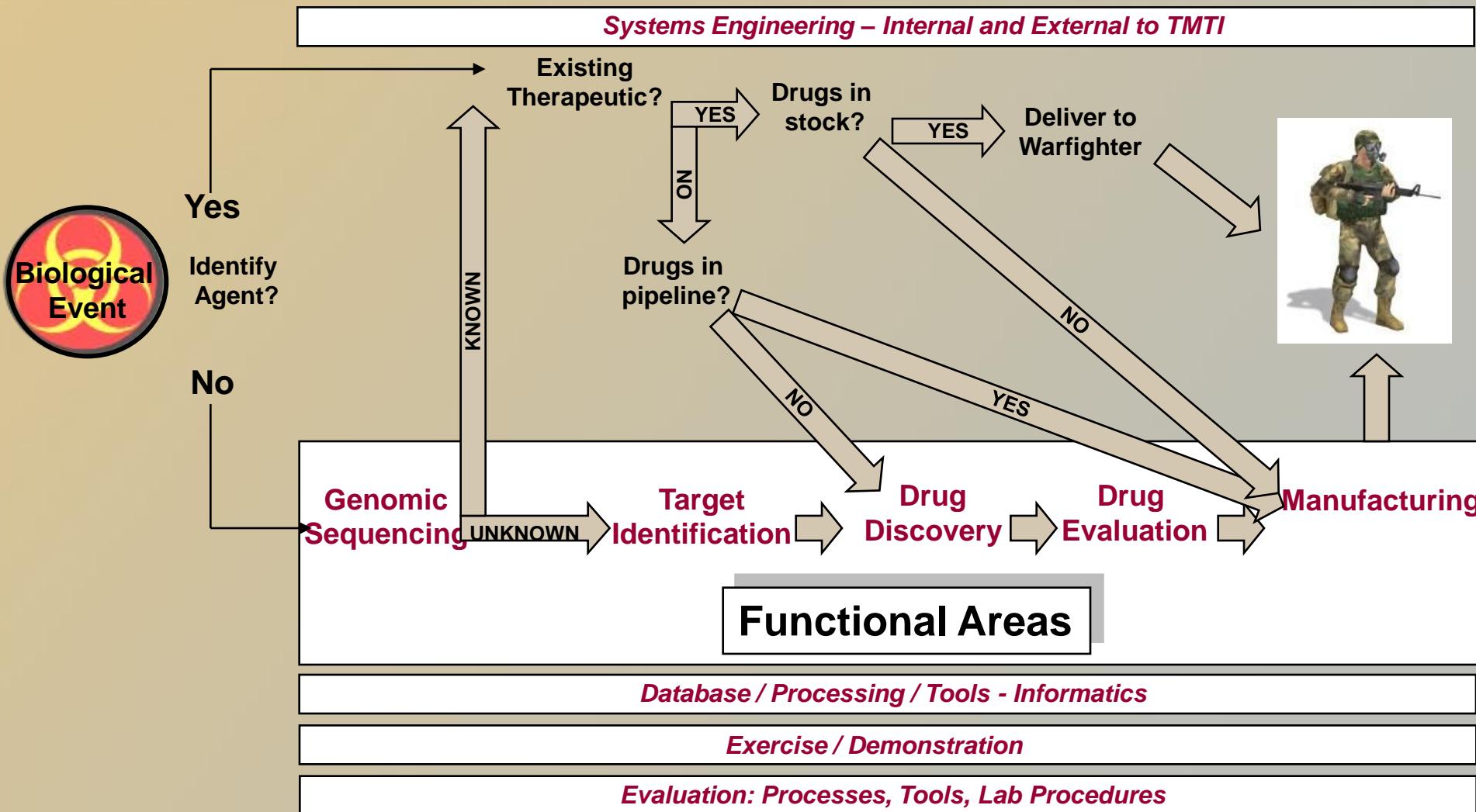
- **Pharmaceutical drug discovery and development is lengthy and expensive**
 - Takes an estimated 8-12 years and up to \$1.2B to bring one drug to FDA licensure
- **Less than 8% of new drugs put into pre-clinical trials ever reach consumers (Bain & Co.)**
 - Costs increase greatly over time
 - For pre-clinical animal experiments
 - One mouse costs ~\$15 ... hence ~\$100,000 is required for an early animal study
 - One non-human primate costs ~\$10,000 ... hence ~\$3M is required for a later stage animal study
 - Human clinical trials are more expensive
 - \$100-800M for Phase I-III human clinical trials
- **Limited commercial market for most biodefense pharmaceuticals**

Research Areas of Interest

- High throughput screening technologies for drug candidates
- Drug design capabilities that push the state of the art
- Technologies to enhance the drug evaluation process (e.g. computer modeling and simulation)

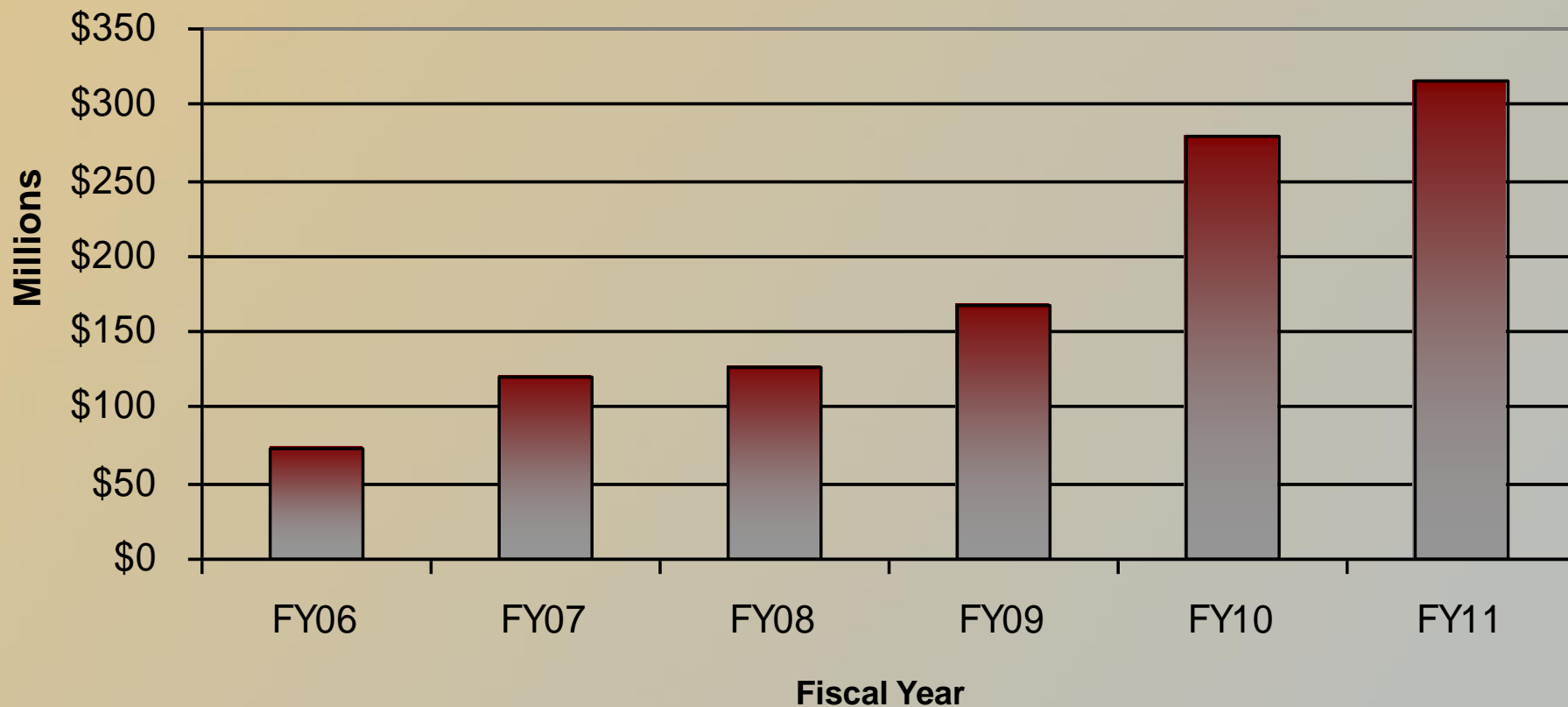


Therapeutic and Technologies Functional Areas



TMTI RDT&E Budget:

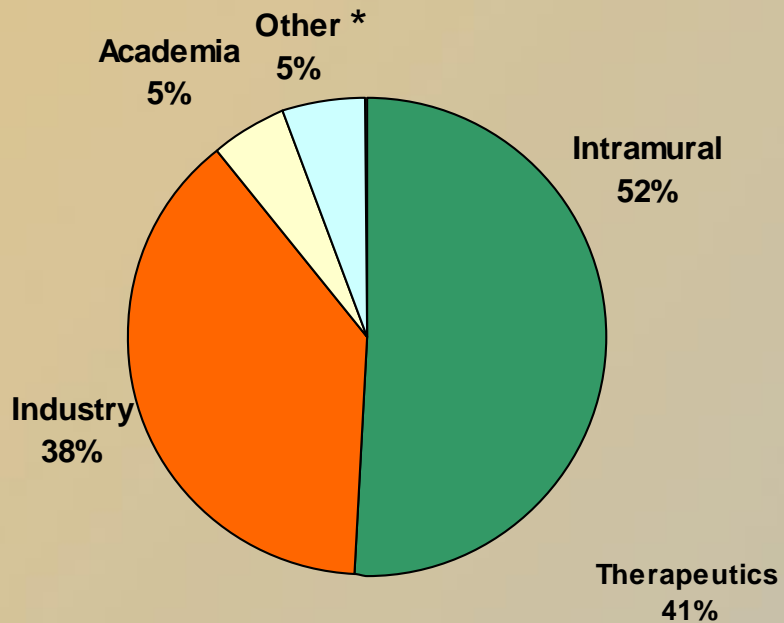
Breakdown by Fiscal Year



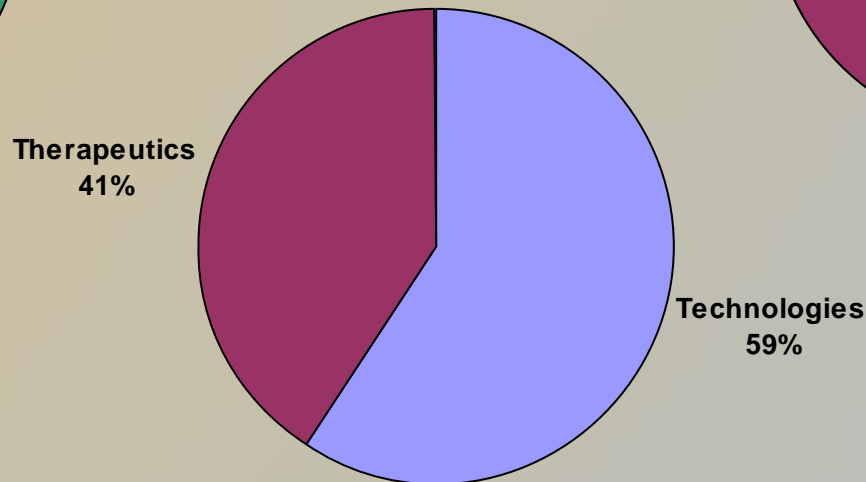
Program Breakdown



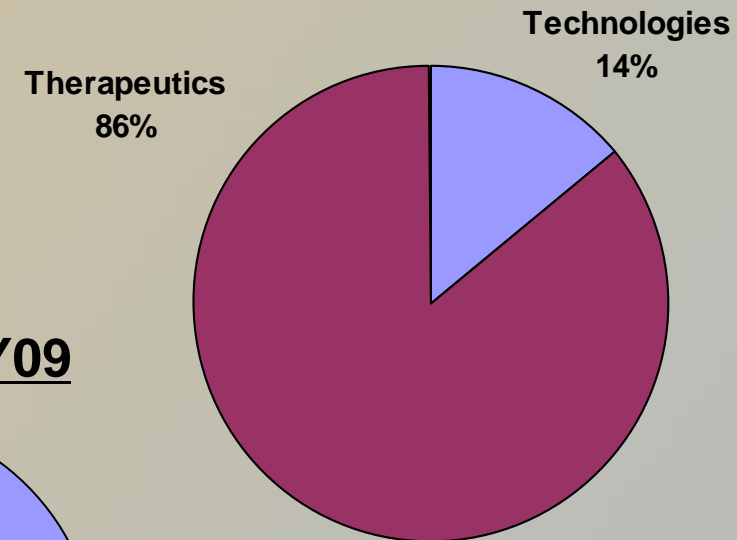
Funding Recipients



Project Distribution FY09



Investment Dollars (FY06-Present)



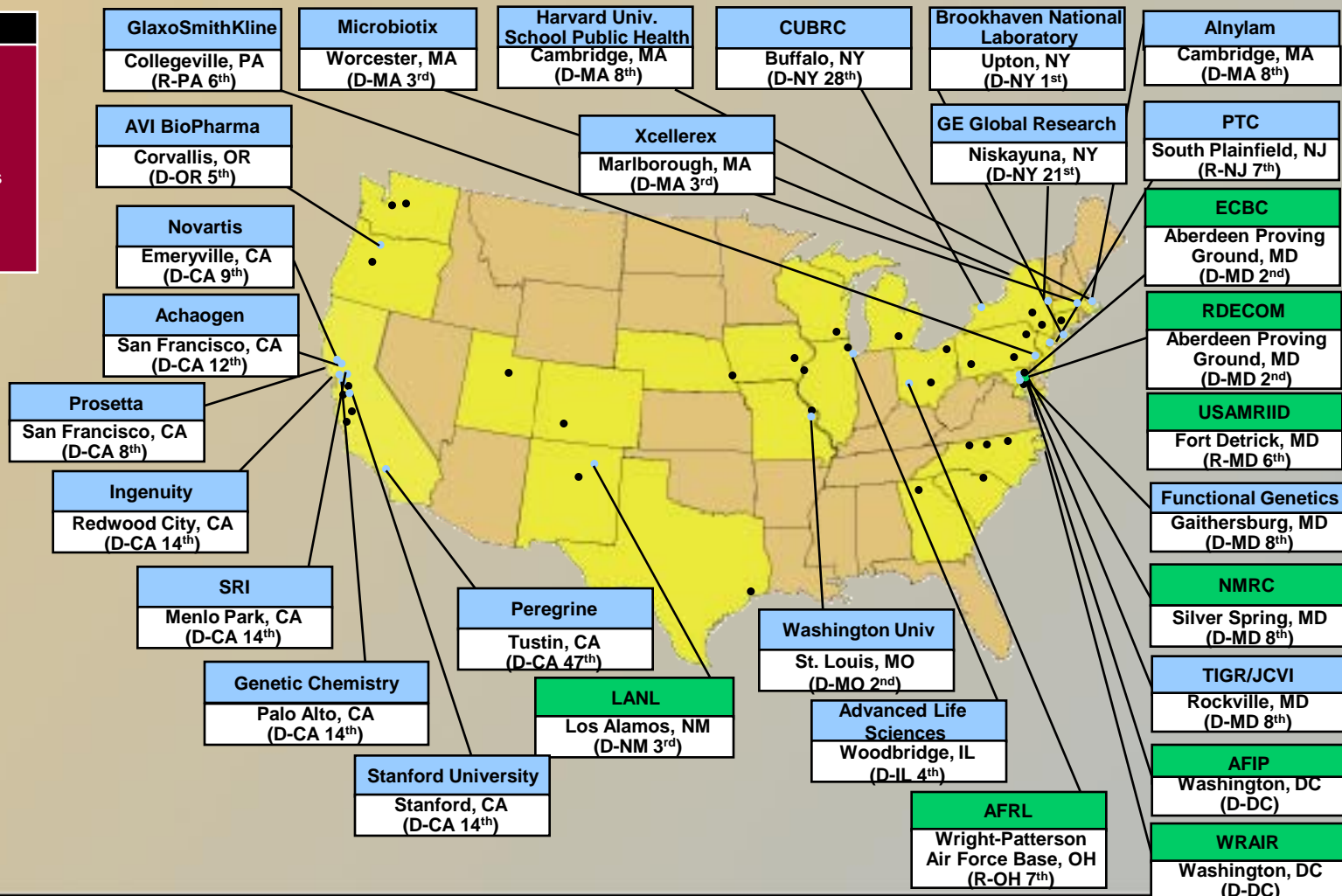
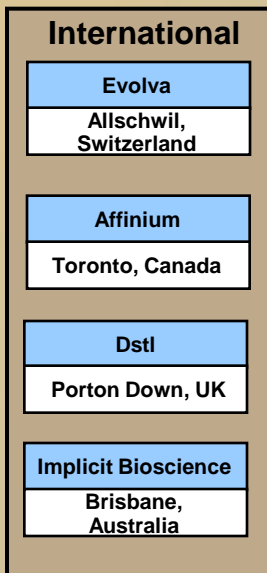
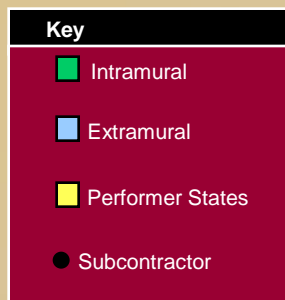
* Other = nonprofit, foreign government

TMTI: A Nationwide Team

FY06-FY10 Performers/Contracts and Subcontractors



Integrating the best efforts within government, academia, DoD, biotech industry, and pharmaceutical industry



Upcoming Business Opportunities



Program	Estimated Target BAA Release	Target Funding Year
Transformational Medical Technology Initiative (TMTI) Email: TMTIwebsite@dtra.mil Website: www.TMTI-cbdefense.org	2QFY10	FY12-13
DTRA "Innovation" BAA FedBizOpps-HDTRA1-07-RDINO-BAA https://www.fbo.gov	Open BAA	FY11
Small Business Innovation Research (SBIR)	1QFY10	FY11
CB Defense Medical S&T Program https://www.fbo.gov	1QFY10	FY11

Summary

- TMTI is developing a response capability to support the Warfighter against biological threats
- Industry is needed to contribute technologies and innovative solutions in order for this effort to be successful
- Key focus areas:
 - Drug candidate high throughput screening
 - Drug design
 - Drug evaluation



How to Contact Us

- The TMTI website provides general information about the TMTI program, its mission, and goals – www.tmti-cbdefense.org
- Official government solicitations can be found at www.fedbizops.gov
- E-mail us directly – tmtiwebsite@dtra.mil
- Call us – 703-767-2347

